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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,190	12/04/2001	Jennifer L. Hillman	PF-0256-3 CON	2435

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EXAMINER
MONSHIPOURI, MARYAM

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 05/14/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/006,190	Hillman et al.
Examiner	**Art Unit**
Maryam Monshipouri	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 3, 9, 10, 17, 18, 20, and 56-68* is/are pending in the application.

4a) Of the above, claim(s) *3, 9, 10, 20, and 62-68* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 17, 18, and 56-61* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on *Dec 4, 2001* is/are a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *3A&6*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Hence, said phrase is considered to be **new matter** with respect to said parent applications and can only benefit priority from the filing date of this application which is 12/4/2001.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Isogai et al. (Database SPTREMBL Accession NO. Q9NPB4, Oct 2000, cited in the IDS). As mentioned above, the examiner could not find support for claims 50 and claim 1 part (c) in parent applications. Thus, for examination purposes it is assumed that the subject matter of said claims can only benefit from the filing date of the instant application. Based on this assumption, Isogai teaches a polypeptide fragment of SEQ ID NO:1 with kinase activity that comprises residues R6 through V23 of SEQ ID NO:1, prior to this application, anticipating claims 1 and 58.

6. ***Claim Rejections - 35 USC § 103***

Applicant's response to restriction requirement filed 2/20/2003 (Paper # 5) is acknowledged. Applicant elected Group I invention directed to claims 1 and 17-18, 56-61 with traverse.

In traversal of restriction requirement applicant argues **(1)** that methods of making and using polypeptides covering the same scope of products could and should be examiner together with the polypeptides from which they depend. Hence, upon determining allowability of polypeptides, applicant would like to presume that method claims which depend from said polypeptides will be rejoined with the elected invention.

Further, according to applicant **(2)** polynucleotides of claim 3 could be examined with the elected invention because a search of prior art to determine the novelty of the polypeptides would substantially overlap with that required for the polynucleotides.

These arguments were fully considered. However, with respect to applicant's **first** argument , it should be noted that currently elected claims are not allowable. Once elected subject matter is identified any processes depending from such allowable subject matter will be considered for rejoining purposes.

In response to applicant's **second** argument the examiner agrees that there may be some overlap between searches required for polypeptides and polynucleotides. However said searches are not coextensive. For example searching for polynucleotides of claim 1 requires a search in class 536/23.2 which is not required for polypeptide claims. Thus, as applicant can appreciate

rejoinder of polynucleotides with elected invention does impose an undue burden of searching on the examiner.

Therefore due to aforementioned reasons restriction is maintained according to previous office action, and is hereby made **final**.

DETAILED ACTION

Claims 1, 17-18, and 56-61 are under examination on the merits. Claims 3, 9-10, 17-18, 20, 62-68 are withdrawn as drawn to non-elected invention. Claims 2, 4-8, 11-16 , 19 and 21-55 are canceled.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1, 17-18, 56-61 are rejected under the judicially created doctrine of double patenting over claims 1-2 of U. S. Patent No. 6,001,624 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: claim 1 of U.S. Patent No. 6,001,624 is drawn to SEQ ID NO:1 of this applicant and fragments thereof, wherein said fragments can inherently comprise polypeptides having at least 95% identity to SEQ ID NO:1 with kinase activity or can comprise residues R6 to V23 of SEQ ID NO:1 with kinase activity. Further the disclosure of said patent (column 8) teaches about HMAK variants having at least 95% identity to SEQ ID NO:1. Further, claim 1 (directed to preferred embodiment , SEQ ID NO:1) of said patent is anticipatory to claims 1, 56-58 of this invention.

With respect to composition claims of this application, it should be noted that claims 17-18 and 59-61 embrace the pharmaceutical compositions of claim 2 of 6,001,624 patent in scope. Further the disclosure of said patent in column 25 teaches about HMAK polypeptides in free solution which can be considered to be a composition comprising HMAK and fragments thereof.

Again, said patent's claim 2, directed to compositions comprising preferred embodiment SEQ ID NO:1, is anticipatory to composition claims 18 and 59-61 of this invention.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 17, 58 and 61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It is noted that this application is a continuation and /or division of the following applications: 09/391,475; 09/225,366; and 08/829,027. However, although the general teaching about fragments of SEQ ID NO:1 was found in all said applications, the examiner could not find support for the phrase "fragments of SEQ ID NO:1 that comprises residues R6 through V23 with adenylate kinase activity" in said parent applications.

Hence, said phrase is considered to be **new matter** with respect to said parent applications and can only benefit priority from the filing date of this application which is 12/4/2001.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Isogai et al. (Database SPTREMBL Accession NO. Q9NPB4, Oct 2000, cited in the IDS). As mentioned above, the examiner could not find support for claims 50 and claim 1 part (c) in parent applications. Thus, for examination purposes it is assumed that the subject matter of said claims can only benefit from the filing date of the instant application. Based on this assumption, Isogai teaches a polypeptide fragment of SEQ ID NO:1 with kinase activity that comprises residues R6 through V23 of SEQ ID NO:1, prior to this application, anticipating claims 1 and 58.

6. ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 17 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isogai et al. (cited above) in view of composition preparation techniques. Isogai teaches (see above) about a fragment of SEQ ID NO:1 with adenylate kinase activity that comprises residues R6 through V23 of SEQ ID NO:1, prior to this application. Isogai does not teach a composition comprising said fragment with a pharmaceutically acceptable excipient.

Current polypeptide composition preparation techniques teach that it is common practice to dissolve useful polypeptides in buffers such as phosphate buffer saline (PBS) or kinase buffer etc. before using them in assays, or injection into mammals (such as rabbits or mice) for antibody preparation. Said buffers can be considered to be pharmaceutically acceptable excipients.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to start with the fragment of Isogai and dissolve it in a suitable buffer before assaying it's activity. One of ordinary skill in the art is motivated to dissolve the polypeptide fragment of Isogai into a buffer because said fragment can be stabilized in said buffer prior to assays of such

fragment, which would practically confirm the activity (kinase or otherwise) of such fragment, rendering the invention obvious.

Finally, one of ordinary skill in the art has a reasonable expectation of success in dissolving said fragment(s) in buffers such as PBS etc., as such methods are routine in the prior art.

9. Claims 1, 17, 57 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamada et al. (J. B.C., 264(32), 19192-19199, 1989, cited in the IDS). Yamada teaches a polypeptide with adenylate kinase activity that has 94% identity to SEQ ID NO:1 of this invention. Even though Yamada''s sequence does not currently display 95% or higher identity with SEQ ID NO:1, using slightly different sequence analysis parameters, can result in an identity of at least 95% or higher of said sequence to SEQ ID NO:1 of this invention, anticipating claims 1 and 57. Figure 10 of Yamada teaches about purification of its polypeptide by column chromatography wherein the buffer comprising said polypeptide before /after loading onto said cloumn(s) can be considered to be a composition comprising pharmaceutically acceptable excipient, anticipating claims 17 and 60.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Maryam Monshipouri, Ph.D. whose telephone number is (703) 308-1083.

The Examiner can normally be reached daily from 8:30 A.M. to 5:00 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. P. Achutamurthy, can be reached at (703) 308-3804. The OFFICIAL fax number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

M. Monshi

MARYAM MONSHIPOURI, PH.D.
PRIMARY EXAMINER